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EXAMINER

LUDLOW, JAN M

ART UNIT PAPER NUMBER

1743

DATE MAILED: 11/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/849,731

Applicant(s)

ITAYA ET AL.

Examiner

Jan M. Ludlow

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 January 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 14 and 18-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 and 15-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 May 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

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1. The examiner notes that the status of the claims is incorrect. Claims 18-20 are withdrawn.
2. Applicant's election with traverse of group I, claims 1-17 in the reply filed on January 12, 2005 is acknowledged. The traversal is on the ground(s) that there is only one inventive concept and there is no burden in searching the additional group. This is not found persuasive because the method of use requires a step of aspiration, whereas the apparatus is merely a housing with a valve at one end. Further, the method claims do not require the structural features of the invention, such as the plunger. There is additional searching burden in searching the method claims because additional terms would be required for the search in electronic searching. The examiner notes that rejection of claim 18 was a typographical error.

The requirement is still deemed proper and is therefore made FINAL.

3. The amendment to the specification filed January 12, 2005 is objected to because "14" was not deleted with the insertion of "12".
 1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the one-way valve for normally urging the plunger as in, e.g., claim 2 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered. Note that the spring and plunger constitute the valve; the valve does not urge the plunger.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

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4. Claims 13, 15-17 are objected to because of the following informalities: In claim 13, line 18, "is remains" is unclear. Appropriate correction is required.
5. Claim 2 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no written description of a one-way valve urging the plunger into place. The spring and plunger within the second chamber constitute the valve.
6. Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 is unclear as a whole because the one-way valve does not urge the plunger—the plunger is urged by the spring, and the plunger, spring and second chamber constitute the valve.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-17 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S.

Patent No. 832,164 to Rutenber.

Referring to claims 1-18, Rutenber discloses a diagnostic pipette assembly including aspiration structure for automation (see FIGS. 1-3). A main pipette housing (A,M) has a hollow interior (M) defining a first chamber and open proximal end and open distal end communicating through the hollow interior (see FIGS. 1-3). It is noted that the ends of the first chamber are open, as liquid enters through the open distal end and air on entry of liquid escapes through opening (S) in extension-tube (Q) proximate to the open proximal end (see FIGS. 1-3). It is also noted that extension-tube (Q) may be interpreted as part of the main pipette housing (A,M) since it is attached to the main pipette housing (A,M) and facilitates venting of air through opening (S) (see FIGS. 1-3). It is also noted that (B) may be interpreted as part of the main pipette housing (A,M) since it is attached to the main pipette housing (A,M) and forms a passage for air (see FIGS. 1-3; PAGE 1, line 47). The main pipette housing (A,M) has an exterior surface (A) having at least one window (P) for viewing diagnostic results (see PAGE 1, lines 92-98). The plurality of windows (P) are on diametrically opposed sides and may be considered a "series of windows" as there is more than one window and they are spaced one after the other.

A pipette tip assembly (C,H) connects with the main pipette housing (A,M) at the open distal end of the main pipette housing (A,M) (see FIGS. 1-3). The distal end of the main pipette housing (A,M) and proximal end of the pipette tip assembly (C,H) have matching tapered surfaces, such that a fluid tight force fit seal is achieved between the main pipette housing (A,M) and pipette tip assembly (C,H) (see FIG. 3). The pipette tip assembly (C,H) has housing with a hollow interior defining a second chamber and an

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open proximal end proximate to the main pipette housing (A,M) at the open distal end of the main pipette housing (A,M) and an open distal end (see FIGS. 1-3). The ends communicate through the second chamber (see FIGS. 1-3). The interior of the pipette tip assembly (C,H) is in communication with the interior of the main pipette housing (A,M) since liquid enters the pipette tip assembly (C,H) into main pipette housing (A,M) (see FIGS. 1-3; PAGE 1, lines 80-86).

The pipette tip assembly (C,H) has a "structure" including plunger, valve, and spring (K) within the second chamber for opening and closing the distal end of the pipette tip assembly (see FIGS. 1-3; PAGE 1, lines 111 and 112; PAGE 2, lines 1-27). The plunger, valve, and spring (K) have a first position wherein the proximal end of the pipette tip assembly (C,H) is opened and the distal end of the pipette tip assembly (C,H) is closed (see FIGS. 1-3; PAGE 1, lines 111 and 112; PAGE 2, lines 1-27). The plunger, valve, and spring (K) are capable of responding to pressure at the distal end of the pipette tip assembly (C,H) by moving to a second position wherein the proximal end of the pipette tip assembly (C,H) remains open and the distal end of the pipette tip assembly (C,H) is open, such that fluid flows from the distal end of the pipette tip assembly (C,H) through the second chamber and into the main pipette housing (A,M) (see FIGS. 1-3). The spring (K) of the "structure" is mostly responsible for urging the plunger to the first and second positions although the interactions among the plunger, valve, and spring (K) of the "structure" must not be ignored in its contribution to urging the plunger (E) (see FIGS. 1-3). For instance, when the plunger contacts a surface of a container with liquid, the weight of the gauge causes valve to open and plunger to move

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upwardly against the action of the spring (K) and permitting liquid to enter the main pipette housing (A,M) into the main pipette housing (A,M) (see FIGS. 1-3; PAGE 1, lines 111 and 112; PAGE 2, lines 1-27). The "structure" includes a one-way valve, which is normally closed to prevent fluid communication among the first and second chambers, but can open to allow the fluid communication (see FIGS. 1-3). It appears valve is a one-way valve, as liquid flows from the distal end of the pipette tip assembly (C,H) and into main pipette housing (A,M) upon contact with a surface of the container holding liquid but does not flow out of the distal end of the pipette tip assembly (C,H) even when the diagnostic pipette assembly is withdrawn from the container as the spring (K) acts to close valve as soon as the diagnostic pipette assembly is withdrawn to prevent the contents of the main pipette housing (A,M) from leaking out (see PAGE 1, lines 111 and 112; PAGE 2, lines 1-27).

The plunger has a first post (I) and second post (F) and an enlarged body in between the post, which is sized and shaped to close off the distal end of the pipette tip assembly (C,H) (see FIG. 3). The second post, which can be depressed and compressed, extends beyond the distal end of the pipette tip assembly (C,H) (see FIG. 3). Comparing to the drawings of the immediate invention, it appears that the spring is mounted on the first post (see FIG. 3). Since the spring (K) surrounds the first post and holds the valve against its seat and valve contacts the spring (K), it appears that the first post may somehow be attached to the spring or the spring may be mounted on the first post (see FIG. 3; PAGE 1, lines 60-80). The first post is adjacent to the connection between the first and second chambers, and it appears that the valve and spring (K) are

connected to the first post (see FIG. 3). The distal end of the first chamber is fit into the proximal end of the second chamber (C,H) for a fluid tight seal (see FIG. 2). The enlarged body has a tapered abutment surface contacting and fitting the tapered abutment surface at the distal end of the second chamber (see FIG. 3).

Therefore, Rutenber includes all the limitations in claims 1-18.

4. Claims 1-5, 7, 8, 11, 13-15 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 1,621,857 to Seraphin.

Referring to claims 1-5, 7, 8, 11, 13-15, Seraphin discloses a diagnostic pipette assembly including aspiration structure for automation (see FIGS. 1-3). A main pipette housing (a,p) has a hollow interior defining a first chamber and open proximal end and open distal end communicating through the hollow interior (see FIGS. 1-3). It is noted that the ends of the first chamber are open, as water enters through ports (e) via valve (g) into the distal end of the hollow interior of the main pipette housing (a,p), gas enters through ports (m) into the proximal end of the hollow interior of the main pipette housing (a,p), and air on entry of liquid escapes through vents (v) or at the end of the handle if the end is left open (see FIGS. 1-3; PAGE 1, lines 78-85; PAGE 2, lines 36-50). It is also noted that handle (o) may be interpreted as part of the main pipette housing (a,p) since it is attached to the main pipette housing (a,p) and facilitates venting of air through vents (v) or at the end of the handle if the end is left open (see FIGS. 1-3; PAGE 1, lines 78-85). It is also noted that (l) may be interpreted as part of the main pipette housing (a,p) since it is attached to the main pipette housing (a,p) and facilitates the entry of gas through ports (m) (see FIGS. 1-3; PAGE 2, lines 45-50). The main pipette housing (a,p)

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has an exterior surface having at least one window (b) for viewing diagnostic results (see PAGE 2, lines 63-70).

A pipette tip assembly (d) connects with the main pipette housing (a,p) at the open distal end of the main pipette housing (a,p) (see FIGS. 1-3). The pipette tip assembly (d) has housing with a hollow interior defining a second chamber and an open proximal end proximate to the main pipette housing (a,p) at the open distal end of the main pipette housing (a,p) and an open distal end (see FIGS. 1-3). The ends communicate through the second chamber (see FIGS. 1-3). The interior of the pipette tip assembly (d) is in communication with the interior of the main pipette housing (a,p) since waters enters the pipette tip assembly (d) through (e) and into main pipette housing (a,p) (see FIGS. 1-3; PAGE 2, lines 36-44).

The pipette tip assembly (d) has a "structure" including plunger (h), valve (g), and spring (k) within the second chamber for opening and closing the distal end of the pipette tip assembly (see FIGS. 1-3; PAGE 1, lines 53-66; PAGE 2, lines 33-44). The plunger (h), valve (g), and spring (k) have a first position wherein the proximal end of the pipette tip assembly (d) is opened and the distal end of the pipette tip assembly (d) is closed (see FIGS. 1-3). The plunger (h), valve (g), and spring (k) are capable of responding to pressure at the distal end of the pipette tip assembly (d) by moving to a second position wherein the proximal end of the pipette tip assembly (d) remains open and the distal end of the pipette tip assembly (d) is open, such that fluid flows from the distal end of the pipette tip assembly (d) through the second chamber and into the main pipette housing (a,p) (see FIGS. 1-3). The spring (k) of the "structure" is mostly

responsible for urging the plunger (h) to the first and second positions although the interactions among the plunger (h), valve (g) and spring (k) of the "structure" must not be ignored in its contribution to urging the plunger (h) (see FIGS. 1-3). For instance, when the plunger (h) contacts a surface of a container with liquid, the weight of the gauge causes valve (g) to open and plunger (h) to move upwardly against the action of the spring (k) and permitting the distal end of the pipette tip assembly (d) to rest on the contact surface of the container and water to enter the main pipette housing (a,p) through ports (e) via valve (g) into the main pipette housing (a,p) (see FIGS. 1-3; PAGE 1, lines 33-44). The "structure" includes a one-way valve (g), which is normally closed to prevent fluid communication among the first and second chambers, but can open to allow the fluid communication (see FIGS. 1-3; PAGE 2, lines 33-70). It appears valve (g) is a one-way valve, as water flows from the distal end of the pipette tip assembly (d) and into main pipette housing (a,p) upon contact with a surface of the container holding liquid but does not flow out of the distal end of the pipette tip assembly (d) even when the diagnostic pipette assembly is withdrawn from the container as the spring (k) acts to close valve (g) as soon as the diagnostic pipette assembly is withdrawn to prevent the contents of the main pipette housing (a,p) from leaking out (see PAGE 2, lines 33-63).

The plunger (h) has a first post and second post and an enlarged body, which is sized and shaped to close off the distal end of the pipette tip assembly (d) (see FIG. 2). Alternatively, it may be interpreted that plunger (h) has a first post and second post and an enlarged body in between the post, which is sized and shaped to close off the distal end of the pipette tip assembly (d), since the body in between the posts is enlarged

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relative to the first or upper post (see FIG. 2). In this alternative, the second post, which can be depressed and compressed, extends beyond the distal end of the pipette tip assembly (d) (see FIG. 2). Comparing to the drawings of the immediate invention, it appears that the spring is mounted on the first post (see FIG. 2). Since the plunger (h) moves against the spring (k), it appears that the first post may somehow be attached to the spring or the spring may be mounted on the first post (see FIG. 2; PAGE 1, lines 58-66). The first post is adjacent to the connection between the first and second chambers, and it appears that the valve (g) and spring (k) are connected to the first post (see FIG. 2). The distal end of the first chamber is fit into the proximal end of the second chamber for a fluid tight seal (see FIG. 2).

Therefore, Seraphin includes all the limitations in claims 1-5, 7, 8, 11, and 13-15.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 5, 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 1,621,857 to Seraphin or U.S. Patent No. 832,164 to Rutenber.

Referring to claims 5, 14, in the event one would argue that the spring is not engaged with or mounted on the first post, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus of Seraphin or Rutenber to have the spring engaged with or mounted on the first post such that the spring has more control over the movement of the first post.

Double Patenting

9. Applicant is advised that should claim 6 be found allowable, claim 10 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

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7. Applicant's arguments filed January 12, 2005 have been fully considered but they are not persuasive.

8. The drawings do not show a one-way valve for normally urging the plunger as claimed, e.g., in claim 2. The spring and plunger together with the second chamber constitute the one-way valve.

9. Applicant argues that Rutenber does not teach a pipette, but the structure is the same as that claimed. Further, Rutenber is a device for the automatic aspiration of a sample for analysis of liquid level and is therefore constitutes "a diagnostic pipette assembly including aspiration structure for automation". Alternatively, in response to applicant's arguments, the recitation " a diagnostic pipette assembly including aspiration structure for automation" has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

Applicant argues there is at most one chamber in Rutenber. This not understood in that Rutenber is highly analogous to the instant structure. The main housing (first chamber) is shown at A, M, and the tip assembly (second chamber) is shown at, e.g., C, G, H. Applicant argues that mounting H would be impossible if there were first and second chambers, but provides no explanation as to why this is so. Applicant makes an

argument concerning the cross-head J, but it is not seen as relevant. The function of the device is explained on page 3, column 1, and it functions in the same way as the instant invention, i.e., F is pressed onto a surface of a vessel and flow communication is established. The instant claims do not preclude the cross-head J. Applicant argues that if there were fluid communication between the tip and head B, there would be no reason for head B to pass air, but head B passes air as the air is displaced from, e.g., tube M by the liquid filling tube M through head C when F is pressed up against the force of the spring to permit fluid entry via a one-way valve. Applicant argues that the instant claims do not require openings L, but the instant claims use open language, e.g., "comprising" and do not preclude this feature. Similarly, the instant claims do not preclude intermediate glass tubes or metallic construction. Applicant argues that "means for evaluating the liquid" are found in the first chamber, but fails to point to any claim language directed to this feature.

With respect to claim 15, the device is capable of automatic aspiration in that fluid is drawn into the device by differential pressure between the fluid head in the cask and atmospheric pressure. Note that no other structure for aspiration is claimed. With respect to claims 13 and 16, two ("a series") of windows P is shown in Figure 1.

10. Applicant argues that Seraphin does not teach a pipette, but the structure is the same as that claimed. Further, Seraphin is a device for the automatic aspiration of a sample for analysis of liquid level and is therefore constitutes "a diagnostic pipette assembly including aspiration structure for automation". Alternatively, in response to applicant's arguments, the recitation " a diagnostic pipette assembly including aspiration

structure for automation" has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

Applicant argues there is at most one chamber in Seraphin. This not understood in that Seraphin is highly analogous to the instant structure. The main housing (first chamber) is shown at, e.g., a, and the tip assembly (second chamber) is shown at, e.g., d, or d below f.

In that applicant indicates that the same arguments are applicable to both Rutenber and Seraphin, the same response to the arguments by the examiner are also applicable.

With respect the alternative rejection under 35 USC 103, applicant has made no argument as to why the reasoning of the examiner is incorrect and the claim limitations are not obvious.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jan M. Ludlow whose telephone number is (571) 272-1260. The examiner can normally be reached on Monday-Thursday, 11:30 am - 8:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Jan M. Ludlow
Primary Examiner
Art Unit 1743

Jml
October 31, 2005